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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Jan BATZER et al.

Confirmation No. 6148
Group Art Unit: 1612

Serial No. : 10/824,102

Examiner: Webb, Walter E

Filed : April 13, 2004

For : COSMETIC OR DERMATOLOGICAL ACTIVE INGREDIENT COMBINATION

APPEAL BRIEF UNDER 37 C.F.R. § 41.37

Commissioner for Patents
U.S. Patent and Trademark Office
Customer Service Window, Mail Stop Appeal Brief - Patents
Randolph Building
401 Dulany Street
Alexandria, VA 22314

Sir:

This Appeal is from the Examiner's rejection of claims 1, 2 and 5-11 set forth in the Final Office Action mailed from the U.S. Patent and Trademark Office on May 27, 2008 and confirmed in the Advisory Action mailed September 12, 2008.

A Notice of Appeal in response to the May 27, 2008 Final Office Action was filed on October 10, 2008 together with a request for a one-month extension of time.

The requisite fee under 37 C.F.R. § 41.20(b)(2) for filing this Appeal Brief is being paid concurrently herewith.

Inasmuch as this Appeal Brief is being filed within the initial two-month period prescribed by 37 C.F.R. § 41.37(a)(1), set to expire December 10, 2008, it is believed that no extension of time is required. However, the Patent and Trademark Office is hereby authorized to charge any fee which may be deemed necessary for maintaining the pendency of this application, including any appeal or extension of time fees that may be deemed necessary, to Deposit Account No. 19-0089.

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I. REAL PARTY IN INTEREST

The real party in interest in this appeal is Beiersdorf AG of Hamburg, Germany. The corresponding assignment was recorded in the U.S. Patent and Trademark Office on September 13, 2004 at REEL 015137, FRAME 0644.

II. RELATED APPEALS AND INTERFERENCES

Appellants, Appellants' representative or the Assignee are not aware of any prior and pending appeals, interferences or judicial proceedings which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

III. STATUS OF CLAIMS

The status of the claims is as follows:

Claims 1-55 are pending in this application.

Claims 3, 4 and 12-55 are withdrawn from consideration (as correctly set forth in the Office Action mailed October 23, 2007; Appellants never have cancelled claims 3, 4 and 12-55).

Each of claims 1, 2 and 5-11 is indicated as rejected in the May 27, 2008 Final Office Action.

The rejection of each of claims 1, 2 and 5-11 is under appeal. Claims 1, 2 and 5-11 involved in the appeal are reproduced in the Claims Appendix attached hereto.

IV. STATUS OF AMENDMENTS

No Amendment has been filed subsequent to the Final Office Action mailed May 27, 2008.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Independent claim 1, the only independent claim under consideration, is drawn to a cosmetic or dermatological preparation that comprises an active ingredient combination of at least one antioxidant or a derivative thereof and 8-hexadecene-1,16-dicarboxylic acid.

See, e.g., page 88, lines 3-5 of the present specification.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The broad issue under consideration is:

Whether claims 1, 2 and 5-11 are properly rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Harding et al., U.S. Patent No. 5,705,144 (hereafter "HARDING") in view of Schonrock et al., U.S. Patent No. 6,296,857 (hereafter "SCHONROCK") and in particular, whether the disclosures of HARDING and SCHONROCK are sufficient to establish a *prima facie* case of obviousness of the subject matter of claims 1, 2 and 5-11.

Appellants assume that, while not expressly stated in the May 27, 2008 Final Office Action, as set forth in the October 23, 2007 Office Action, claims 1 and 2 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting

as allegedly being unpatentable over several claims of copending Application Nos. 11/087,395, 11/547,104, 10/871,819 and 11/157,946. These provisional rejections are not being presented for review in this appeal. Upon indication of allowable subject matter, Appellants will file one or more Terminal Disclaimers which address all obviousness-type double patenting rejections which may still be warranted.

VII. ARGUMENTS

A. Citation of Authority

Obviousness

The appropriate starting point for a determination of obviousness is stated in *Graham v. John Deere Co.*, 383 U.S. 1, 17, 148 U.S.P.Q. 459, 466 (1966):

> Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined.

The test of obviousness *vel non* is statutory and requires a comparison of the claimed subject matter as a whole with the prior art to which the subject matter pertains. *In re Brouwer*, 77 F.3d, 422, 37 U.S.P.Q. 2d 1663 (Fed. Cir. 1996); *In re Ochiai*, 71 F.3d 1565, 37 U.S.P.Q. 2d 1127 (Fed. Cir. 1995).

Often, it will be necessary to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. This analysis should be made explicit. There must

be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1740-1741. "A patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *Id*, at 1741.

"If the Examiner fails to establish a *prima facie* case, the rejection is improper and will be overturned." *In re Rijckaert*, 9 F.3d, 1532, 28 U.S.P.Q.2d, 1956 (Fed. Cir. 1993), citing *In re Fine*, 837 F.2d 1071, 1074,5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988).

B. Claims 1, 2 and 5-11 Are Not Properly Rejected Under 35 U.S.C. 103(a) As Being Unpatentable Over HARDING in View of SCHONROCK

1. Summary of Rejection

The rejection (as set forth in the October 23, 2007 Office Action) alleges that HARDING teaches a composition for lightening skin which comprises a dioic acid of a general structure which encompasses 8-hexadecene-1,16-dicarboxylic acid, and that HARDING also teaches that the composition further contains cosmetic adjuncts such as antioxidants. The rejection concedes that HARDING fails to teach folic acid. In this regard, the rejection relies on SCHONROCK and asserts that this document teaches a method for cosmetically lightening large areas of the skin comprising the antioxidant folic acid. In view thereof, the Examiner essentially takes the position that, absent a

showing of unexpected results, it would allegedly have been obvious to one of ordinary skill in the art to incorporate folic acid into the compositions of HARDING.

2. Response

a. The general formula of HARDING encompasses about thousand different dioic acids

According to, e.g., claim 1 of HARDING the dioic acids for use in combination with retinol or a derivative thereof are of general formula

$$COOH\text{-}(C_aH_b)\text{-}COOH$$

wherein a is an integer of from 6 to 20 and b is an integer of from 8 to 40.

Even if only (unbranched) saturated dioic acids are considered, this formula encompasses 15 different acids (with a total of 8 to 22 carbon atoms).

Further, the shortest (unbranched) mono-unsaturated acid (a = 6) already has three isomers, each of which has two stereoisomers (cis- and trans-isomers). The longest (unbranched) mono-unsaturated acid (a = 20) has 10 isomers, each with two stereoisomers. Accordingly, the above formula encompasses a total of 3 + 4 + 4 + 5 + 5 + 6 + 6 + 7 + 7 + 8 + 8 + 9 + 9 +10 + 10 = 101 different mono-unsaturated acids (not taking into account stereoisomers), 8-hexadecene-1,16-dicarboxylic acid being only one example of the altogether 7 (seven) different hexadecene-1,16-dicarboxylic acids.

Of course, in the case of (unbranched) di-unsaturated dioic acids the number of possible isomers which are encompassed by the above formula is significantly higher. For example, for a = 6, there are already six isomeric di-unsaturated dioic acids (without stereoisomers). For a = 20 there are 108 isomeric di-unsaturated dioic acids (without stereoisomers). Accordingly, the above general formula of HARDING encompasses

about thousand different saturated, mono-unsaturated and di-unsaturated dioic acids (without counting stereoisomers).

The rejection does not explain why one of ordinary skill in the art would have had an apparent reason to choose 8-hexadecene-1,16-dicarboxylic acid from the host of different dioic acids which are encompassed by the general formula set forth by HARDING, i.e., which is neither expressly mentioned nor hinted at in this document.

b. HARDING is silent as to the availability of 8- hexadecene-1,16-dicarboxylic acid

Appellants further point out that unlike for many other dioic acids which are encompassed by the general formula of HARDING, this document fails to provide any indication as to how 8-hexadecene-1,16-dicarboxylic acid can be obtained from either a commercial source or by a synthetic route from readily available starting materials.

For example, according to HARDING C_8-C_{16} saturated dioic acids are available commercially from chemical suppliers (col. 3, lines 28-29) and C_{17}-C_{22} saturated or unsaturated dioic acids can be manufactured by fermentation using certain yeasts (col. 3, lines 30-33).

With respect to C_8-C_{16} unsaturated dioic acids HARDING mentions in col. 3, lines 43-46 that these acids can be produced using the method disclosed in EP 341 796, further details of which are provided in the following passages of this document. According to col. 4, lines 1-26 of HARDING, it can be predicted that by using oleic acid as a substrate in this method, a mixture of 8 different mono-unsaturated dicarboxylic acids may be produced, whereas linoleic acid is expected to afford a mixture of 13 di-unsaturated dicarboxylic acids and linolenic acid is predicted to afford a mixture of 12 di-

and tri-unsaturated dicarboxylic acids. None of these mixtures is expected or predicted to contain any isomer of 8-hexadecene-1,16-dicarboxylic acid. This is yet another factor why HARDING fails to provide an apparent reason for contemplating 8-hexadecene-1,16-dicarboxylic acid as a dioic acid for use in the compositions of HARDING.

c. There is no statement in HARDING which would make 8-hexadecene-1,16-dicarboxylic acid appear to be an attractive choice of a dioic acid for the purposes of HARDING

It further is noted that HARDING lacks any teaching or suggestion to the effect that any of the dioic acids having 16 carbon atoms, whether saturated, mono- or di-unsaturated, is an attractive choice as dioic for use in providing a composition for topical application to human skin which comprises a dioic acid and retinol or a derivative thereof. On the contrary, not only is none of the seven isomers of hexadecene-1,16-dicarboxylic acid employed in any of the numerous exemplified compositions of HARDING, but not a single one of the dioic acids which are employed in the numerous exemplified compositions of HARDING, whether saturated, mono- or di-unsaturated, contains 16 carbon atoms. In particular, the dioic acids which are employed in the Examples or listed in Tables 3-6 of HARDING comprise exclusively 8, 9, 12, 14, 18 or 22 carbon atoms. This is at least a strong indication for one of ordinary skill in the art that dioic acids having 10, 11, 13, 15, 16, 17, 19, 20 and 21 are not particularly desirable for the purposes of HARDING. At the very least, this fact is a disincentive rather than a motiviation for one of ordinary skill in the art to employ these dioic acids instead of dioic acids comprising 8, 9, 12, 14, 18 or 22 carbon atoms in a composition according to HARDING.

d. A genus does not automatically suggest each and every species which is encompassed by the genus

Appellants submit that at least the totality of the facts set forth above provides evidence that there is no apparent reason for one of ordinary skill in the art to contemplate a dioic acid having 16 carbon atoms and in particular, 8-hexadecene-1,16-dicarboxylic acid for use in providing a composition according to HARDING.

In this regard, it is noted that according to page 3, first paragraph of the Advisory Action mailed September 12, 2008 "it is the offices [*sic*] position that a prior art genus of many species suggests every species falling within that genus". Appellants submit that this statement is contrary to established case law: "The fact that a claimed compound may be encompassed by a disclosed generic formula does not by itself render that compound obvious." *In re Baird*, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994)); see also *In re Jones*, 958 F.2d 347, 350, 21 USPQ2d 1941, 1943, *In re Deuel*, 51 F.3d 1552, 1559, 34 USPQ2d 1210, 1215 (Fed. Cir. 1995), and MPEP 2144.08.

For example, MPEP 2144.08 I. prescribes:

When a single prior art reference which discloses a genus encompassing the claimed species or subgenus but does not expressly disclose the particular claimed species or subgenus, Office personnel should attempt to find additional prior art to show that the differences between the prior art primary reference and the claimed invention as a whole would have been obvious. Where such additional prior art is not found, Office personnel should consider the factors discussed below to determine whether a single reference 35 U.S.C. 103 rejection would be appropriate.

e. HARDING in view of SCHONROCK fails to render obvious the use of folic acid in combination with any dioic acid

Regarding the antioxidants which may be present in the compositions of HARDING, it is pointed out that this document mentions antioxidants only in passing as one of many optional components of the compositions disclosed therein. Moreover, the

only example of an antioxidant mentioned in HARDING, i.e., butylated hydroxytoluene, is a known antioxidant for foods (in contrast to, e.g., folic acid) and therefore, one of ordinary skill in the art would understand that antioxidants (and in particular, antioxidants which have nothing in common with butylated hydroxytoluene) do not play any special, let alone a critical role for the intended effect of the compositions of HARDING but may rather be employed, if at all, merely in order to protect various other components of the composition from oxidation. The importance (or better: lack thereof) of antioxidants for the compositions according to HARDING is further illustrated by the fact that none of the compositions of the Examples of HARDING contains any antioxidant (not even butylated hydroxytoluene) and that HARDING does not even set forth a suitable concentration range for (any) antioxidants.

What SCHONROCK has in common with HARDING is that the former document also mentions antioxidants only as optional components of the compositions disclosed therein and also clearly fails to convey the impression that antioxidants play any particular, let alone critical role for the intended effect of the compositions disclosed therein.

Appellants note that the Examiner relies on col. 12, lines 49-54 and appears to allege that this passage suggests (or even teaches) that antioxidants "play a role in lightening of skin". Appellants respectfully disagree with the Examiner in this regard.

Specifically, SCHONROCK makes it absolutely clear that the only substances which are responsible for the skin lightening effect of the compositions described therein are the oligopeptides set forth in columns 1-5 thereof (see, e.g., title and col. 1, lines 60-64 and col. 10, lines 7-15). Antioxidants are mentioned in SCHONROCK only among a

number of optional components which are "conventionally used" in cosmetic and dermatological preparations (see col. 12, lines 38-48). Further, the passage in col. 12, lines 49-54 of SCHONROCK relied on by the Examiner states:

> It is also advantageous to add customary antioxidants to the preparations in accordance with the present invention. Advantageous antioxidants which may be used in accordance with the invention are all those antioxidants which are suitable or conventional for cosmetic and/or dermatological applications.

It is not seen that the above passage teaches or suggests that antioxidants are critical or even only desirable components of the compositions of SCHONROCK, let alone critical components for achieving the desired effect of skin lightening.

Further, SCHONROCK fails to provide any explanation at all as to why it is "advantageous" to add customary antioxidants to the preparations disclosed therein. In this regard, it is noted that many other passages of SCHONROCK also use the terms "advantageous" and "advantageously" (see, e.g., columns 13 and 14). This makes it clear to one of ordinary skill in the art that these terms are not meant to specifically highlight particularly advantageous (optional) components of the compositions of SCHONROCK but merely are to indicate that the presence of these components is associated with the conventional advantages thereof.

f. There is no apparent reason for combining (specific passages of) HARDING and SCHONROCK

Appellants point out that there is no reason for combining HARDING and SCHONROCK because the compositions disclosed therein are entirely different with respect to their essential components. Further, even one were to assume, *arguendo*, that there is motivation for one of ordinary skill in the art to combine the teachings of

HARDING and SCHONROCK, it is not seen that such a combination would focus on passages of these documents which relate to optional components of the compositions disclosed therein.

In this regard, it also needs to be taken into account that the disclosure of SCHONROCK with respect to antioxidants cannot be expected to add anything of particular advantage or importance to the disclosure of HARDING. In particular, both HARDING and SCHONROCK mention antioxidants as optional components without pointing out any effect of these components which would go beyond their conventional effect. In addition, none of the exemplary compositions of HARDING contains any antioxidant and it is not seen that SCHONROCK, i.e., a document which itself fails to suggest that antioxidants are important components of the compositions disclosed therein, provides an apparent reason for one of ordinary skill in the art to add any of the antioxidants mentioned therein, let alone folic acid, to the compositions of HARDING.

Appellants submit that for at least all of the forgoing reasons, the Examiner has failed to establish a *prima facie* case of obviousness of present claim 1 (and the claims dependent therefrom).

g. Claims 9 to 11

Dependent claims 9 to 11 recite concentration ranges of 8-hexadecene-1,16-dicarboxylic acid in the compositions according to claim 1. While HARDING discloses general concentration ranges of dioic acid(s) which (slightly) overlap the concentration ranges recited in claims 9 to 11, the concentration of the dioic acid(s) in the compositions

of the various Examples of HARDING is at least 15 % by weight and is in most cases 20 % by weight, i.e., significantly higher than the upper values of the concentration ranges which are recited in present claims 9 to 11.

It further is submitted that one of ordinary skill in the art will understand that the broad concentration range for the dioic acids of 0.1 to 30 % given in HARDING for use in conjunction with retinol or a derivative thereof is due to the fact that the general formula of HARDING encompasses about two thousand different compounds (including stereoisomers) which can be expected to show a broad range of activity. One of ordinary skill in the art will also understand that the fact that HARDING prefers a concentration range of 5 to 20% and employs dioic acids in the compositions exemplified therein in a concentration of not less than 15% reflects the need for sufficient activity of the dioic acids in the compositions disclosed therein.

In this regard, it also needs to be taken into account that claim 1 of HARDING recites that an effective amount of from 0.1 to 30% by weight of a dioic acid must be employed. Accordingly, HARDING clearly does not suggest that each and every dioic acid encompassed by the general formula disclosed therein will be effective (and can be employed) at a concentration of 0.1% but rather teaches that an effective (or at least very desirable) amount in most cases will be at least 15%, i.e., the minimum concentration of dioic acid(s) employed in the Examples of HARDING.

Moreover, a closer analysis of the Examples of HARDING shows that the required (effective) concentration of the dioic acids disclosed therein appears to increase with the number of C atoms. Specifically, the only acids which are employed in a concentration of 15% (see Examples 3 and 9) are azelaic acid (nine carbon atoms) and a

C_8 mono-unsaturated dioic acid. All of the other acids (having 12 to 22 carbon atoms) are employed in a (total) concentration of 20%. In view thereof, HARDING may even be considered to teach away from the subject matter of present claims 9-11.

Appellants submit that the foregoing are additional reasons (i.e., in addition to the reasons set forth above with respect to claim 1) why the Examiner has failed to establish a *prima facie* case of obviousness of the subject matter of present claims 9 to 11.

VIII. CONCLUSION

Appellants respectfully submit that for at least all of the foregoing reasons, the Examiner has failed to establish a *prima facie* case of obviousness of any of claims 1, 2 and 5-11 over HARDING in view of SCHONROCK, which is a prerequisite for maintaining a rejection under 35 U.S.C. § 103. The Board is, therefore, respectfully requested to reverse the Final Rejection, and to allow the application to issue in its present form.

Respectfully submitted,
Jan BATZER et al.

Neil F. Greenblum
Reg. No. 28,394

December 3, 2008
GREENBLUM & BERNSTEIN, P.L.C.
1950 Roland Clarke Place
Reston, VA 20191
(703) 716-1191

Heribert F. Muensterer
Reg. No. 50,417

CLAIMS APPENDIX

1. A cosmetic or dermatological preparation comprising an active ingredient combination of at least one antioxidant or a derivative thereof and 8-hexadecene-1,16-dicarboxylic acid.

2. A preparation as claimed in claim 1, wherein the at least one antioxidant is selected from the group consisting of imidazoles, peptides, carotenoids, α-lipoic acid, lipoamide, aurothioglucose, propylthiouracil and other thiols, metal chelators, humic acid, bile acid, bile extracts, bilirubin, biliverdin, unsaturated fatty acids, folic acid, flavenoids, tocopherols, rutinic acid, ferulic acid, butylhydroxytoluene, butylhydroxyanisole, nordihydroguaiaretic acid, nordihydroguaiaretic acid, trihydroxybutyrophenone, kojic acid, uric acid, mannose, zinc and salts thereof, selenium compounds and enzymatic antioxidants.

5. A preparation as claimed in claim 1, wherein the at least one antioxidant is present in a concentration of 0.001 to 30% by weight, based on the total weight of the preparation, and does not include vitamin E or derivatives thereof.

6. A preparation as claimed in claim 1, wherein the at least one antioxidant is present in a concentration of 0.05 to 20% by weight, based on the total weight of the preparation, and does not include vitamin E or derivatives thereof.

7. A preparation as claimed in claim 1, wherein the at least one antioxidant is present in a concentration of 0.1 to 10% by weight, based on the total weight of the preparation, and does not include vitamin E or derivatives thereof.

8. A preparation as claimed in claim 1, wherein the at least one antioxidant is present in a concentration of 0.001 to 10% by weight, based on the total weight of the preparation, and includes vitamin E or derivatives thereof.

9. A preparation as claimed in claim 1, wherein the 8-hexadecene-1,16-dicarboxylic acid is present in a concentration of 0.001 to 10% by weight, based on the total weight of the preparation.

10. A preparation as claimed in claim 1, wherein the 8-hexadecene-1,16-dicarboxylic acid is present in a concentration of 0.005 to 8% by weight, based on the total weight of the preparation.

11. A preparation as claimed in claim 1, wherein the 8-hexadecene-1,16-dicarboxylic acid is present in a concentration of 0.05 to 5% by weight, based on the total weight of the preparation.

EVIDENCE APPENDIX

None.

RELATED PROCEEDINGS APPENDIX

None.